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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,941	04/30/2001	James F. Hemerick	6530.0278	8636

22852 7590 09/17/2003

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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/843,941

Applicant(s)

HEMERICK ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,45 and 47-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,45 and 47-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The Final Rejection mailed June 3, 2003 is hereby withdrawn. The amendment filed September 3, 2003 has been entered.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the feature of the translucent region having a length that substantially coincides with a constrained length of the stent must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification refers to the distal end of the outer tubular structure as being "clear" (paragraph 39) while the claims include the term "translucent". The specification should be amended to include the term "translucent". Further, the specification should be amended to include the claimed feature that the translucent region has a length that substantially coincides with a constrained length of the stent.

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Claims 58 and 66 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 58 does not further limit the subject matter of claim 57 which is dependent on claim 56. Claim 66 has a similar problem.

Claims 11, 45 and 47-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is confusing and inaccurate since the distal end of the inner elongate structure (at 117) does not substantially coincide with the distal end of the outer tubular structure 105 since tip 117 extends distally beyond the distal end of outer tubular structure 105 as seen in figure 5b. The stent defined in claim 61 has already been defined in claim 11, lines 5-6 ("a constrained length of stent within the outer tubular structure") resulting in a double recitation of the same element.

The indicated allowability of claims 11, 45 and 47-52 is withdrawn in view of the newly discovered reference(s) to Bartholf et al. (2001/0034549). Rejections based on the newly cited reference(s) follow.

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Claims 11, 45, 48, 50-55 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Bartholf et al. (2001/0034549). Winston et al. show outer tubular structure 20, inner elongated structure 12, stent accommodating area (just distal to flange 14) and a plurality of external tubular structure contact areas (flanges 14) which slide against the interior surface of the outer tubular structure 20 since they are shown contacting one another in figures 1, 2 and 4. Winston et al. fail to disclose a translucent region at the distal end of the outer tubular structure 20. However, Bartholf et al. teach that the distal end region of the outer tubular structure of a stent delivery system should transmit light therethrough so that the stent therein may be visually inspected (paragraphs [0034] and [0037]). It would have been obvious to enable the distal end region of the outer tubular structure 20 of Winston et al. to transmit light therethrough so that it too would have this advantage. The Bartholf et al. distal end region of the outer tubular structure is "translucent" as claimed since the stainless steel braiding 70 and teflon layer 69 diffuse the light to some extent. Further, the length of this translucent region substantially coincides with a constrained length of the stent as seen in figures 2 and 3. As to claims 48 and 50, Winston et al.

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fail to disclose at least one marker band on the inner elongated structure. However, Bartholf et al. teach that the inner elongated structure of a stent delivery system should include a marker band 22 in order to provide an indication of whether or not the stent has been completely deployed (paragraph [0031]). It would have been obvious to include a marker band on the on the inner elongated structure 12 of Winston et al. so that it too would have this advantage. As to claim 51, Winston et al. fails to disclose the steps of retracting the stent back into the outer tubular structure and then repositioning the stent delivery system. However, retracting the Winston et al. stent back into the outer tubular structure and then repositioning the stent delivery system when it is determined that the stent is not initially properly positioned would have been obvious since it was well known in this art to so retract and reposition stents for this reason. As to claim 53, Winston et al. fail to show Pellethane as the material for the inner tubular structure. However, using Pellethane as the material for the inner tubular structure would have been obvious since it is well known as a desirable material for this use as indicated on page 2, lines 8-10 of applicant's specification.

Claims 47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Bartholf et

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al. (2001/0034549) as applied to claims 11, 45, 48, 50-55 and 61-63 above, and further in view of Hofmann et al. (5,810,837). Winston et al. fail to disclose a gap between an external surface of the external tubular structure 14 and the inner surface of the outer tubular structure 20. However, Hofmann et al. teach that there should be a gap between the external surface of the external tubular structure 10 and the inner surface of the outer tubular structure 3 (the outer diameter C of member 10 is 4.5 mm while the inner diameter B of outer tubular structure 3 is 4.6 mm as indicated in col. 4, line 38) apparently in order to insure that the inner elongated structure 10, 9, 7 is able to slide relative to outer tubular structure 3 with minimal friction. It would have been obvious to provide such a gap between the Winston et al. external surface of the external tubular structure 14 and the inner surface of the outer tubular structure 20 so that it too would have this advantage.

Claims 56-60 and 64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Bartholf et al. (2001/0034549) as applied to claims 11, 45, 48, 50-55 and 61-63 above, and further in view of Burns (5,100,381). Winston et al. fail to disclose each subsequently proximal external structure 14 increasing in durometer. However, Burns teaches that

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the distal portion of a catheter should be more flexible than the proximal portion in order to allow the catheter to be advanced through the rather tortuous paths of the arteries while maintaining pushability (col. 2, lines 30-34 and col. 3, line 65 to col. 4, line 6). It would have been obvious to make the distal portion of the Winston et al. catheter 12 more flexible than the proximal portion so that it too would have this advantage. With this modification, the distal portion of the Winston et al. catheter 12 (which includes a distal flange 14) would be made of a material which is more flexible (with a low durometer) than a proximal portion of the catheter 12 (which includes a proximal flange 14) made of a high durometer, stiffer material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
September 11, 2003



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731